EXHIBIT G

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 15-2666 (JNE/FLN)
This Document Relates to All Actions	**EXPERT REPORT OF DR. MICHAEL J. STONNINGTON**

I. EDUCATIONAL BACKGROUND AND QUALIFICATIONS

A. *Medical Education and Training:*

I am a Board Certified Orthopedic Surgeon with a special interest in Total Joint Replacement and Traumatology. My educational background includes graduating from the University of Virginia with a BA, followed by graduating from Duke University Medical School with a MD. I completed my residency in Orthopedic Surgery at the University of Florida. I have nearly 20 years of post-residency experience in general orthopedic surgery, total joint replacement surgery, and complex orthopedic trauma surgery. My experience includes being a former staff Orthopedic Surgeon in the United States Air Force for 3 years on Active Duty (a total of 15 years in the Air Force Reserves). I achieved the rank of Lt. Col before leaving the Air Force. A true and correct copy of my Curriculum Vitae is attached as Exhibit A.

B. *Clinical Experience as an Orthopedic Surgeon:*

I have been in private practice (Southern Bone and Joint Specialists, PA) in Hattiesburg, MS for almost 17 years. I work at a Major Tertiary Referral Hospital in Southern Mississippi (Forrest General Hospital), an Orthopedic Specialty Hospital (The Orthopedic Institute), and an Outpatient Surgery Center (Southern Surgery Center). I typically perform over 250 total joint replacement surgeries a year. I also perform many other types of orthopedic surgeries and am the only Pelvic and Acetabular Orthopedic Trauma surgeon in Southern Mississippi. I specialize in total joint replacement surgery and complex pelvic and acetabular surgery. I have extensive experience with revision total joint replacement surgery. At Forrest General Hospital (a hospital with over 400 physicians), I have been Chairman of Surgery and President of Staff (Chief of Staff). I am currently President Elect of Staff (for the second time).

C. *Medical/Legal Work Experience:*

I have consulted as a treating physician on defective hip implant cases involving problems relating to metal-on-metal hip implant design, failure, and impact on patients. I have testified as a treating surgeon in numerous cases, but never in a courtroom. Until recently I served as a professional consultant for an orthopedic brace company known as Futuro. In the past four years, I have been retained and deposed one time as an expert witness in a legal matter, *Kenneth Urbahns vs. Memorial Hospital at Gulfport*, Cause No. A2401-16-152. My compensation rates for work as an expert witness are as follows:

$750/hr for research;

$1500/hr for depositions;

$15,000/day for courtroom testimony.

D. *Methodology for Developing Opinions:*

In developing the opinions contained in this report, I have relied primarily on my medical training, education, and knowledge, as well as my clinical experience in the field of orthopedic surgery and joint replacement. In addition, I may rely to a lesser extent on my review of relevant literature, the reports of other experts, and deposition testimony given in this case. The complete list of materials I have reviewed and relied upon in forming my opinions is attached hereto as Exhibit B. I reserve the right to amend the opinions in this report if further information becomes available to me.

II. ORTHOPEDIC SURGERY, INFECTION RATES, AND THE ROLE OF PATIENT WARMING

A. *Prevalence of Total Joint Replacements and Risk of Infection:*

Orthopedic Surgery is an important field of surgery that touches almost all families in some way. Virtually every family in the United States has members who have arthritis and painful joints which may require surgical intervention. Approximately 7 million people in the United States have a hip or knee replacement (Ref #34). Over one million hip or knee replacements are performed in the United States yearly (Ref #35). With the ñbaby boomersò aging and the increasing rate of arthritis diagnoses, the annual numbers of total joint replacements will substantially increase. Total joint replacements are projected to be the most common elective procedures in the near future (Ref #36, #37). With total joint surgery comes the potential for revision surgery as well. The numbers of combined total joint replacements and revision joint replacements will continue to increase as the population ages. It is, therefore, imperative that complications be kept to a minimum. In particular, infection of total joint replacements is a devastating and potentially life-threatening complication. Infected total joints often lead to revision total joint replacements ï most often with a minimum of two more surgeries. Even with infection rates as low as 2% or less for total joint replacements, the absolute numbers of infected total joints are staggering (given the incidence of total joint replacements) (Ref #45). Moreover, the actual incidence of total joint infections is likely substantially underestimated by the orthopedic community (Ref #39). Given these numbers, the need to keep infection rates down is not only a paramount concern for orthopedic surgeons, but it is a paramount public health issue.

B. *Patient Warming Modalities and Use of the Bair Hugger:*

Anesthesiologists have widely used patient warming devices during many surgical procedures. Medical authorities who support thermoregulation agree that as long as the patient is warmed in a safe manner that prevents them from becoming hypothermic, no single or specific means of patient warming is required.

One popular method of patient warming that has gained favor over the past thirty or more years is ñforced air warmingò or ñFAW.ò FAW is a mechanism used in the operating room to warm patients in order to minimize the chances of patients developing hypothermia. While some authorities have claimed that a reduction in superficial SSIôs may be realized by use of FAW, my review of the evidence supporting this hypothesis demonstrates it to be based on a single study of colorectal patients, published in 1996 (Ref #1). There is no evidence that thermoregulation reduces the incidence of joint infections. Indeed, it is my understanding that no such study has ever been undertaken. Nonetheless, there is compelling evidence that some forms of FAW, including the Bair Hugger system, generate increased microbial load at the surgical site and therefore increase the risk of infections in orthopedic surgeries.

In this report, I will discuss the importance of attempting to minimize known sources of contamination in the operating room environment, especially in orthopedic surgery cases. Bair Hugger devices will be shown to present an unnecessary increased risk of infection for implant surgeries such as total joint replacements. For all of these reasons, it is my opinion that Bair Hugger warming should no longer be used in surgical implant cases. In fact, I have ceased using Bair Hugger devices in my practice.

III. AVOIDANCE OF INFECTION RISK IN ORTHOPEDIC DEVICE SURGERY

A. *History of the Operating Room Environment and Risk of Airborne Contamination:*

From the inception of operating rooms, surgeons and medical staff have endeavored to reduce the risk of infections that result from surgery. As surgery advanced over time, knowledge of microbes improved and the sources of infections became more well known. This knowledge is not static and grows year by year. Unfortunately, throughout history there have been regrettable instances where advances in this knowledge have been ignored or mocked. A very prominent instance involved a pioneer of antiseptic techniques in surgery. Dr. Ignaz Semmelweis was a Hungarian physician who discovered that infections such as ñchildbed feverò (or medically known as puerperal fever) could be diminished drastically in obstetrical clinics by simply washing the studentsô and doctorsô hands with a disinfectant. Obviously he was correct, but in the mid-19th century, his views were counter to accepted medical opinions. Dr. Semmelweisôs recommendations only became accepted years after his untimely and tortured death (Ref #41). Because Dr. Semmelweisôs views were not accepted (and actually mocked), countless lives were unnecessarily lost. Surgeons are charged to protect their patients and to diminish infection risks as much as is humanly possible. It is paramount for them not to repeat history by ignoring growing evidence of infection sources, such as the growing evidence of contaminants within Bair Hugger devices.

A 2007 study estimated, that in the year 2002, there were approximately 1.7 million Health Care-Associated Infections (HAIs) in the USA. The estimated deaths in US hospitals that were associated with theses HAIs were a staggering 98,987 individuals (Ref #10). A New England Journal of Medicine Survey showed that device associated infections combined with surgical site infections accounted for 47.4% of all HAIs (Ref #46). Obviously, as noted previously, these numbers are a huge public health issue.

Orthopedic surgeons know that it takes a very small number of colony-forming units (CFUs) to create an infection in an implantable prosthesis, because the prosthesis itself has no blood supply and can easily serve as a ñplatformò for microbes to attach to and form biofilms (Ref #42). Because of this known risk, ñextraò steps are taken by orthopedic surgeons to reduce the risk of deep joint infections (ñDJIôsò). These measures include things such as rigorous hand cleaning/washing protocols, ensuring that the operating room is ñultra clean,ò limiting the numbers of personnel in the operating room, sterilization of instruments, proven skin antisepsis techniques, and more.

In addition to the above measures, the air in the operating room needs to be as sterile as possible. Of course, we do not have the ability to make operating rooms 100% sterile. But once a controllable infection risk is recognized, the goal is always to remove that controllable risk to the largest extent possible.

In order to control the risk of contaminated air reaching the surgical wound, modern orthopedic surgeries are conducted in operating rooms with specialized ventilation systems. These systems direct a flow of air downward towards the surgical site. Theater ventilation systems are only designed to keep the surgical area clean. Other areas of the room, such as below the operating table, are not sterile. Surgical residents are trained to keep their hands above the table at all times because the area beneath the OR table is considered non-sterile. Indeed, the goal of theater ventilation is to continuously introduce freshly-filtered air to the surgical site while preventing the unclean surrounding air from entering that area.

Properly functioning theater ventilation will prevent most, if not all, airborne contaminants from reaching the surgical site. Medical research shows that airborne contamination is correlated with postoperative joint replacement infections (Ref #22, #26, #27, #44). In addition, airborne bacteria can deposit in surgical wounds (Ref #28-32). Research has also shown that the density of airborne particles in the vicinity of the surgical wound correlates with airborne bacterial counts (Ref #33). The bacteria in this same research were primarily gram-positive cocci, a common cause of total joint replacement infections (Ref #33). Having known sources of increased particle counts and bacterial, disease-producing organisms located in operating room equipment is contrary to the goal of maintaining a sterile operating room environment. Therefore, it is incumbent on physicians, especially those involved in high risk procedures such as orthopedic device surgeries, to ensure the removal of unnecessary potential sources of airborne bacteria from the operating room. As will be discussed further below, there is clear evidence that the Bair Hugger devices harbor pathological contamination and increase particle counts in the operating room, thus compromising the surgical environment and increasing patient risk of developing infections.

B. *Inadequate Filtration and Contamination of the Bair Hugger Devices:*

The BH devices are contaminated with pathogens and disrupt airflow. As a result, Bair Hugger devices are not used in any of my surgeries. Orthopedic surgeons never want to use a device in the OR that could increase the risk of periprosthetic joint infections, particularly when there are equally effective modes of warming a patient during surgery. Microbial contaminants, like the particles shown in experimental studies, can easily be mobilized by air currents into an operative field (Ref #3, #4, #18, #32). The risk of deep joint infections is increased with foreign body implants such as knee or hip replacements. It only takes a small number of bacterial colony

forming units to contaminate a wound and then propagate into a superficial or deep infection (particularly in the presence of a foreign body) (Ref #2).

For fields where contamination is a potentially devastating complication (e.g., orthopedic surgery), ORs often use high-efficiency particulate air (HEPA) ventilation. HEPA filtration meets filtration efficiency standards of 99.97% at 0.3 microns. The filtration efficiency is the method by which the filterôs effectiveness is assessed. Although the Bair Hugger FAW device is advertised as having a 0.2 micron filter, 3M (the manufacturer) does not indicate the filtration efficiency of the filter (Ref #7). In testing, FAW blowers have been shown to emit airborne contamination into an OR environment despite the use of the filter (as opposed to a HEPA filter) (Ref #3).

The internal system of a Bair Hugger has been shown to be prone to microbial colonization despite the filter. For example, studies show that the filter is not consistently preventing a microbial build up within the internal system (Ref #4-6). The Bair Hugger filter allows 5%-7% of airborne contamination to pass through it into the FAW blower exit hose and the Bair Hugger has been shown to have a 92% internal colonization rate (Ref #7). In this same study, 15% of isolates were skin-specific organisms including Staphylococcus Aureus species. Skin flora organisms were found in Bair Hugger devices in another study. The microbial contaminants in this study included Staphylococcus Aureus and Staphylococcus Epidermidis, both of which are very common bacteria in total joint infections. Fungal microbial contaminants have also been cultured from the internal system of Bair Hugger devices, including their air stream and hoses (Ref #4-7, 19).

Researchers have established that numerous microbial contaminants are indeed present in the air streams exiting the hoses attached to the Bair Hugger devices (Ref #4). Furthermore, in another study, 32% of Bair Hugger units studied were emitting internally generated airborne contamination (Ref #3). In a 2013 study, researchers found 70% of 23 Bair Hugger devices, in a single hospitalôs operating rooms, were emitting contaminated particles from their hose ends. The same devices had significant internal buildup of microbial contamination in inaccessible air path surfaces (Ref #19). These internal air path surfaces could never be accessed and thereby never cleaned by hospital employees. In this same study, newer generation Bair Hugger devices were found to have reduced filtration efficiency compared to older models (and therefore less effective filters in newer models). Compared to previous studies, the internal contamination and emission of contaminated particles from the hoses appears to be significantly higher (Ref #19). In addition, these researchers showed that the microbial contaminants of these newer generation units matched microbes which had a high association with SSIs (e.g. 76% detection rate of Coagulase Negative Staphylococcus) (Ref #19). Essentially, the devices had become a storage cell for contaminants ï contaminants which were easily capable of being ejected from the unit into the FAW hose.

As discussed further below, having a device in the operating room that harbors known contamination is anathema to the orthopedic surgeonôs goal of attenuating risks of infection in the surgical environment. Cross-contamination from Bair Hugger devices is a very serious concern. Microbial contaminants collected within the units (from previous OR cases) will likely be transferred via the hose to future operative fields. The devices are routinely in the vicinity of freshly contaminated floors of an operating room. Under these circumstances, there is simply no reasonable basis to refute the mounting evidence that these devices take in and harbor harmful

microorganisms found in the hospital environment. Based on the foregoing, and within a reasonable degree of medical probability, it is my opinion that the lack of adequate filtration in the Bair Hugger devices causes contamination to circulate in the OR and over the operative field, which increases the risk of patientsô developing peri-prosthetic joint infections (ñPJIôsò).

C. *Operating Room Airflow Disruption with Bair Hugger and Increased Risk of Infection:*

Surgical staff in the OR generate airborne desquamated skin cells (a large percentage of which carry microbial contaminants) (Ref #8-9). Clinical trials have shown that 80-90% of bacterial contaminants isolated in surgical wounds come from colony forming units in operating room air (Ref #11). Bacteria, viruses, and fungi can be carried by skin cells floating in the air. These skin cells are constantly being generated by personnel and patients in the operating room. Studies have shown a significant relationship between air contamination in the operating room air and SSI occurrences (Ref #12-13). The disruption of the engineered airflow in the operating room by the Bair Hugger devices, which will be discussed further below, significantly increases the risks of these contaminants to infect an implant patient. The human traffic around Bair Hugger devices coupled with the data from numerous airborne and FAW studies (as outlined in this paragraph and preceding paragraphs), yield a higher risk for a contaminated operating room.

Bair Hugger devices have been shown to generate hot air convection currents which disrupt ventilation airflows over the surgical site. (Ref #17-20, 43) This is very concerning because these disrupted airflows were also shown to result in air flow patterns that would carry buoyant detergent bubbles from contaminated regions into sterile regions (Ref #14, #20). Given that skin cells and bacteria have similar airborne characteristics as bubbles (Ref #15, #16), these studies have elucidated how contaminants migrate from non-sterile regions to sterile operative wounds under a mass flow of FAW, i.e., air from a Bair Hugger device. Another study showed how FAW increases the particle count over the surgical wound (Ref #17). These particles can easily carry bacteria. A follow-up study by the same authors showed that waste heat from Bair Hugger devices significantly disrupted unidirectional airflow (Ref #18). The warmed air (from waste heat) disrupted the downward unidirectional air flow by flowing up against it. The warmed air then cooled above the operative field and subsequently flowed back down into the operative field. Particle counts were again shown to be significantly increased over the surgical site (Ref #18). Increased particle counts combined with deleterious airflow patterns demonstrate once more how contaminants can migrate from non-sterile fields into sterile fields.

A clinical study of patients in a United Kingdom hospital found a higher incidence of infected total joint replacements in Bair Hugger patients versus non-Bair Hugger patients (Ref #20). This significantly raises concern for patient safety, particularly in light of the same studyôs well designed air flow study (which definitively shows deleterious contaminated air flow patterns). Furthermore, laminar air flow studies prior to the introduction of Bair Hugger devices showed significant reductions in infection rates (Ref #21, #22). But since the widespread usage of Bair Hugger devices, some laminar air flow studies have shown increased infection rates (Ref #23-25). It begs the question whether this increased infection rate is due to laminar airflow, or whether contaminated Bair Hugger air being mobilized into sterile wounds is to blame. Based on the data generated by recent studies and my own observations, the most likely cause of these increased infection rates is the use of Bair Hugger warming devices and not use of laminar or unidirectional airflow.

Although there is a study indicating that Bair Hugger blankets add a possible secondary filter for contaminants, the study involved only two trials, hardly enough to render a statistically significant conclusion (Ref #4). The hypothesis that the blanket acts as a secondary filter therefore remains unproven and lacks any support in real-world experience. In fact, a recent case report shows that the blanket does not prevent internal soot from being transferred from the Bair Hugger device and then blown through the blanket and onto the patient (Ref #40). If the blanket does not stop soot, it will not stop microbes. It therefore does not act as a secondary filter.

In short, the cumulative data show that airborne bacteria in an operating room will frequently contaminate a surgical wound. To become infected, a wound requires contamination by microorganisms. Air cannot be 100% sterile, but known sources of contamination must be removed to decrease the degree of air and wound contamination. As previously stated, contaminated air from the Bair Hugger machine travels through the hose, into the blankets, and such contamination cannot be reliably ñfiltered outò by the blanket itself. Additionally, the heat exhaust of the Bair Hugger contributes to mobilization of particulates from non-sterile areas, allowing them to travel to the surgical site. Such contamination has ready access to the sterile field, increasing a patientôs infection risk. A device that mobilizes contaminated air in the vicinity of a surgical field can therefore create contaminated surgical wounds, and hence, infected wounds or joint replacements. To conclude otherwise is to defy science and reason, and is contrary to the overwhelming weight of mounting evidence based on published literature showing the risks outlined above.

Based on the foregoing, it is my expert opinion to a reasonable degree of scientific probability, that the Bair Hugger system causes an increased risk of patient infection because of substantial scientific evidence that the waste heat generated by the Bair Hugger warming units disrupts operating room airflow conditions and contributes to mobilization of microbes in the area of the sterile field. Again, the spread of pathogenic contamination from the Bair Hugger machines to the operative field make these devices unreasonably dangerous because they significantly increase the risk of deep joint infections, especially during orthopedic device surgeries.

IV. CONCLUSION/SUMMARY OF OPINIONS

In summary, airborne contaminants in the Operating Room are analogous to bullets on a battlefield. The greater the numbers of bullets, the more likely soldiers are to be injured or killed. Contaminated air flow is the same when it comes to surgical patients. Microbes, if allowed to exist unchecked in the operating room, will find their way into their ñbattlefieldò - the sterile field. Bair Hugger machines harbor, release, and mobilize these ñbulletsò into the sterile field, increasing the patientsôrisks of life-threatening and debilitating infections. In many patients, these microbial ñbulletsò will ñstrikeò a wound and result in an infection. These infections have the potential of causing a catastrophic outcome. Morbidity and mortality become grave issues in patients with infections, particularly patients with infected total joint replacements. Bair Hugger devices are a definite source of contaminated airborne particles, and, as such, should not be allowed to remain in the surgical environment.

Although the Bair Hugger was developed to improve outcomes, the devices have become "weaponized" with microbes. Needless to say, the operating room is not a battlefield, but the analogy to a battlefield "environment" is compelling, given the risks to life and limb that patients (like soldiers) face in every surgery. Based on the literature cited and reports I have considered, it is my opinion to a reasonable degree of medical probability that use of the Bair Hugger in orthopedic surgeries disrupts operating room airflow and exposes patients to pathogenic contamination, thereby increasing the risk of infection in every orthopedic implant surgery case where it is used. Given this known risk, along with the existence of other equally effective means of warming patients, use of Bair Hugger warmers is unreasonably dangerous. Specifically, there is now ample evidence to support the fact that other forms of patient warming are far safer and equally effective at maintaining optimal core body temperature as compared to the Bair Hugger. For this reason, I no longer use the Bair Hugger FAW system, and I recommend that surgeons and other clinicians give serious consideration to use of alternative forms of patient warming such as conductive fabric blankets or warming systems that do not suffer from the filtration, contamination, and air-disturbance defects demonstrated by the Bair Hugger system. Any form of patient warming that does not suffer from the design flaws of the Bair Hugger should be used as an alternative to minimize patient infection risks. I hold all these opinions to a reasonable degree of medical probability.

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Exhibit B
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